

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

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HORIZON PHARMA IRELAND  
LIMITED, et al.,

Civil No. 14-7992 (NLH/AMD)

Plaintiffs,

**OPINION**

v.

ACTAVIS LABORATORIES, UT,  
INC., et al.,

Defendants.

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**HILLMAN, District Judge**

Before the Court is the motion of Plaintiff Horizon (Horizon Pharma Ireland Limited, HZNP Limited and Horizon Pharma USA, Inc.) for reconsideration (Docket No. 192) of the Court's August 17, 2016 Markman Opinion (Docket No. 188). Horizon is the current owner and assignee of the patents-in-issue and of the PENNSAID® 2% New Drug Application, which is the first FDA-approved twice-daily topical diclofenac sodium formulation for the treatment of the pain of osteoarthritis of the knees.

Horizon has filed several Hatch-Waxman actions alleging patent infringement against generic companies seeking to market copies of Horizon's PENNSAID® 2% formulation prior to the expiration of Horizon's patents, and this particular action concerns Horizon's claims against Actavis Laboratories UT, Inc.

("Actavis").<sup>1</sup> Horizon brought this action<sup>2</sup> in response to Actavis' assertion that the generic copy of PENNSAID® 2% described in Actavis' Abbreviated New Drug Application No. 207238 ("ANDA"), if approved by the FDA, would not infringe any valid and enforceable patent owned by Horizon.

In the Markman phase of the case,<sup>3</sup> the Court was tasked with construing the following terms in the '838 Patent Family<sup>4</sup>:

- A. "the topical formulation produces less than 0.1% impurity A after 6 months at 25°C and 60% humidity"
- B. "the formulation degrades by less than 1% over 6 months"
- C. "consisting essentially of"

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<sup>1</sup> Another group of cases filed by Horizon against a generic company seeking to market copies of Horizon's PENNSAID® 2% formulation prior to the expiration of Horizon's patents is against Lupin Ltd. and Lupin Pharmaceuticals, Inc. Because the Court's findings in the Actavis actions directly impact the claims in the Lupin actions, Lupin filed a brief in opposition to Horizon's motion for reconsideration and appeared at the January 4, 2017 hearing on that motion. (See Civil Action No. 15-3051, Docket No. 137.)

<sup>2</sup> This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202 and 35 U.S.C. § 271.

<sup>3</sup> Claim construction is "an issue for the judge, not the jury." Markman v. Westview Instruments, Inc., 517 U.S. 370, 391 (1996).

<sup>4</sup> There are nine patents asserted in this matter. Of these, five patents - U.S. Patent Nos. 8,252,838; 8,563,613; 8,871,809; 9,066,913; and 9,101,591 - are part of the "'838 Patent Family" and all agreed to have the same specification. The other four patents - U.S. Patent Nos. 8,546,450; 8,217,078; 8,618,164; and 9,132,110 - are part of the "'450 Patent Family" and similarly agreed to have the same specification.

The Court found each of these terms to be indefinite. (Docket No. 188 at 12, 14, 27.) Specially with regard to "consisting essentially of," the Court noted that Horizon identified five basic and novel properties for the claimed invention: (1) better drying time; (2) higher viscosity; (3) increased transdermal flux; (4) greater pharmacokinetic absorption; and (5) favorable stability. (Id. at 23.) The Court found that the basic and novel property of "better drying time" was indefinite, which therefore caused the term "consisting essentially of" to be indefinite. (Id. at 27.)

Horizon has filed the instant motion for reconsideration, arguing that the Court erred in two ways:

The Court did not consider the alleged "indefiniteness" on a claim-by-claim basis, but instead broadly held the term "consisting essentially of" to be indefinite. When claims requiring use of hydroxypropyl cellulose (HPC) as a thickening agent are considered as independent inventions, those claims should not be found to be indefinite because the test results for such inventions are consistent. The only evidence of alleged inconsistent testing results was in the context of different claimed inventions that require carbopol thickening agents; and

The Court's finding of indefiniteness is based on allegedly "unrebutted" expert testimony that the patent discloses two methods for comparing drying rates, which provide inconsistent results. However, Horizon's responsive expert evidence on this issue was not presented to the Court because of an agreement between the parties to not brief the definiteness of "greater drying rate" in Responsive Markman briefs. At the time of the Markman briefing and Markman Hearing, Actavis had not sought leave to amend their contentions to include the argument that the basic and novel properties were themselves indefinite. Indeed, to date, the only indefiniteness argument presented with respect to

"consisting essentially of" in Actavis' Contentions is that a person of ordinary skill ("POSA") cannot identify the basic and novel properties.

(Docket No. 192-1 at 7.) Horizon also objects to the Court's application of Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120, 2129 (2014) to the analysis of the invention's basic and novel properties. (Docket No. 192-1 at 10.)

The Court will grant Horizon's request that it reconsider its Markman decision, but after having fully considered the parties' briefing and oral argument, the Court stands by its prior findings.<sup>5</sup>

With regard to Horizon's argument that it was precluded from fully presenting its evidence to support its construction

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<sup>5</sup> A motion for reconsideration may be treated as a motion to alter or amend judgment under Fed. R. Civ. P. 59(e), or as a motion for relief from judgment or order under Fed. R. Civ. P. 60(b), or it may be filed pursuant to Local Civil Rule 7.1(i). The purpose of a motion for reconsideration "is to correct manifest errors of law or fact or to present newly discovered evidence." Max's Seafood Cafe ex rel. Lou-Ann, Inc. v. Quinteros, 176 F.3d 669, 677 (3d Cir. 1999). A judgment may be altered or amended only if the party seeking reconsideration shows: (1) an intervening change in the controlling law; (2) the availability of new evidence that was not available when the court granted the motion for summary judgment; or (3) the need to correct a clear error of law or fact or to prevent manifest injustice. Id. A motion for reconsideration may not be used to re-litigate old matters or argue new matters that could have been raised before the original decision was reached, P. Schoenfeld Asset Mgmt., L.L.C. v. Cendant Corp., 161 F.Supp.2d 349, 352 (D.N.J. 2001), and mere disagreement with the Court will not suffice to show that the Court overlooked relevant facts or controlling law, United States v. Compaction Sys. Corp., 88 F.Supp.2d 339, 345 (D.N.J. 1999).

of the term "better drying time," the Court does not agree. The timeline of events, detailed by Actavis in its presentation at the January 4, 2017 hearing, demonstrates that Horizon had ample notice of Actavis's indefiniteness challenge to "better drying time," and several opportunities - including during the two Markman hearings on March 2, 2016 and June 7, 2016, the supplemental briefing in between, and during the ten weeks after the second Markman hearing and the issuance of the Court's Markman Opinion on August 17, 2016 - to voice its concerns about presenting all of its evidence to support its construction of "better drying time."

Similarly, Horizon chose to present its position on the '838 Patent Family as a whole, and has only raised the request that each claim of every patent should be considered individually in its motion for reconsideration. It is clear that Horizon was not "sandbagged" by the course of the claim construction process that took place over many months.

Even considering, however, Horizon's belated arguments to support its construction of "better drying time" and request for claim-by-claim construction, the Court comes to the same conclusion as detailed in the Markman Opinion. As the Court summed up its analysis, (1) the specification describes two different methods for evaluating "better drying time," and the two methods do not provide consistent results at consistent

times, (2) the claimed results are not seen across all formulations of the claimed invention, and when "dryness" is evaluated at any time shorter than four hours, not all formulations of the claimed invention actually exhibit "better drying time," and (3) Horizon's expert Dr. Walters' reasoning does not comport with the plain language of the specification, and his references to the prosecution history do not provide any clarity on the appropriate time frame under which to evaluate the drying rate, while Actavis' expert Dr. Kohn is more persuasive that a POSA would not know under what standard to evaluate the drying rate of the claimed invention. (Docket No. 188 at 26-27.) Thus, Horizon's requested relief in its motion for reconsideration, even if granted, does not change the Court's conclusion.

Putting aside the construction of "better drying time," the finding that the term "consisting essentially of" is indefinite is also confirmed by the finding that the stability and degradation claims are indefinite. As noted above, one of the basic and novel properties of Horizon's claimed invention is "favorable stability." The Court did not specifically address this term in the context of assessing the definiteness of the basic and novel properties, but earlier in the Markman Opinion the Court extensively analyzed the terms "the topical formulation produces less than 0.1% impurity A after 6 months at

25°C and 60% humidity” and “the formulation degrades by less than 1% over 6 months.” In construing those terms, the Court found that the identity of “impurity A” was unknowable to a reasonable certainty to a POSA. (Docket No 188 at 7-12.) The Court further found that the patent did not provide guidance on how to evaluate degradation because it was either equated with “impurity A”, which had already been deemed indefinite, or could be determined by multiple methods for how to evaluate stability without further guidance. (Id. at 7-13.) Thus, the Court concluded that both terms relating to stability were indefinite.<sup>6</sup>

The finding that the claim terms relating to stability are indefinite renders the claim term “consisting essentially of” indefinite. This is because the basic and novel property of “favorable stability” is indefinite. As stated in the Court’s Markman Opinion, if a POSA reading the patent would understand the five principles identified by Horizon to be the basic and novel properties of the claimed invention, then once one of them is indefinite, they all become problematic. (Id. at 27.) When one property does not have “reasonable certainty,” it follows that the group of properties itself does not have the requisite “reasonable certainty.” Consequently, the term “consisting

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<sup>6</sup>Horizon has not specifically challenged this finding in its motion for reconsideration.



essentially of" must be construed as indefinite due to the inability for a POSA to have "reasonable certainty" about what the basic and novel properties of the invention are, and the POSA would lack "reasonable certainty" about whether an additional ingredient would materially alter the basic and novel properties of the claimed invention. (Id.) Thus, regardless of the Court's construction of "better drying time," the indefiniteness of the stability terms also warrants the finding that "consisting essentially of" is indefinite.

Finally, with regard to Horizon's argument that the standard for an indefiniteness analysis reiterated by the Supreme Court in Nautilus should not be performed as to the basic and novel properties, the Court stands by its Markman Opinion, which explained why Nautilus should, and does, apply here. (Id. at 17-23.)

Horizon's bases for reconsideration were ably briefed and argued at the January 4, 2017 hearing, such that Horizon persuaded the Court to reconsider its August 17, 2016 Markman Opinion. But after reconsideration, the Court is not persuaded to disturb the prior result.

An appropriate Order will be entered.

Date: January 6, 2017  
At Camden, New Jersey

s/ Noel L. Hillman  
NOEL L. HILLMAN, U.S.D.J.